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**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

ATTY.'S DOCKET: DONMICHAEL=27

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| In re Application of: | ) | Art Unit: 3731 |
| | ) | |
| T. Anthony DON MICHAEL | ) | Examiner: HO, U. |
| | ) | |
| Appln. No.: 10/005,699 | ) | Washington, D.C. |
| | ) | |
| Filed: December 7, 2001 | ) | Confirmation No. 7636 |
| | ) | |
| For: DISTAL PROTECTION DOUBLE BALLOON CATHETER | ) | February 3, 2004 |

**RESPONSE**



Honorable Commissioner for Patents
2011 South Clark Place
Crystal Plaza Two, Lobby, Room 1B03
Arlington, VA 22202

Sir:

This is in response to the Examiner's Action dated November 21, 2003, the contents of which have been carefully considered.

The rejection of claims 1, 7, 9 and 10 as anticipated by Leone is respectfully traversed for the reason that the system defined in these claims, and particularly in parent claim 1, is not disclosed in the applied reference.

The present invention is directed to a medical treatment system that includes a catheter having an annular bypass flow lumen and inlet and outlet openings extending from the lateral surface of the catheter. In addition, as defined in claim 1, the bypass flow lumen terminates distally at a location between the outlet openings and the distal end of the catheter. These features are illustrated in figures 1 and 3 of the application drawing. Figure 3 shows a bypass flow lumen 22 that is annular, while figure 1 shows that the outlet

openings communicating with the bypass flow lumen extend from the lateral surface of catheter 12 and that lumen 22 terminates at a location upstream of the distal end of the catheter.

Simply stated, none of the features described above is disclosed in the applied reference. The only detailed illustration of a bypass flow lumen is shown in figure 3 of the patent drawing where the bypass lumen, which is referred to in the patent specification as a profusion lumen, is given the reference numeral 38. Clearly, this lumen is not annular.

A number of the patent drawings, and in particular figure 9, show that the outlet of the profusion lumen is at the very distal end of the catheter, and does not extend from the lateral surface of the catheter. In fact, the specification states most explicitly, at column 2, lines 61-62, that the outlet opening, or perfusion port 36, is located at the distal tip 18 of catheter 10.

Thus, it should be readily apparent that claim 1 distinguishes over this reference at least by the following recitations:

> an annular bypass flow lumen surrounding, and isolated from, said guidance lumen;
>
> outlet openings extending from said lateral surface (of said catheter) and communicating with said bypass flow lumen; and
>
> wherein said bypass flow lumen terminates distally at a location between said outlet openings and said distal end of said catheter.

Accordingly, it is requested that the prior art rejection presented in section 3 of the action be reconsidered and withdrawn, that the rejection presented in section 5 of the action be withdrawn in view of the dependency of the rejected claims from claim 1, that all of the claims be allowed and that the application be found in allowable condition.

If the above amendment should not now place the application in condition for allowance, the Examiner is invited to call undersigned counsel to resolve any remaining issues.

Respectfully submitted,

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